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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,726	01/22/2004	Susan M. Danehower	PC24990A	5624

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PATENT DEPARTMENT, MS8260-1611
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EXAMINER	
CAPPS, KEVIN J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,726	DANEHOWER ET AL.	
	Examiner	Art Unit	
	Kevin Capps	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This Office Action is in response to the Remarks and Amendments filed on August 3, 2006. Claims 1-3 and 5-14 are pending and examined on the merits herein.

2. In light of Applicant's amendment of claim 1 deleting the word "and", the objection against claims 1-3 and 5-14 is withdrawn.

3. In light of Applicant's amendments removing the multiple dependencies, the objection against claims 6 and 10-14 is withdrawn.

4. In light of Applicant's amendment clarifying the claims as to the identity of the "related compounds" of tolterodine, the rejection of claim 2 under 35 USC § 112, second paragraph, is withdrawn.

5. The rejection of claims 1-3 and 5-14 under 35 USC § 102(e) over Nilvebrant et al. (US 6,630,162) is maintained. The rejection is restated to address Applicant's amendments. Applicant's arguments are addressed below.

6. Applicant's statement of common ownership of WO 00/27364 is acknowledged. However, the rejection of claims 1-3 under 35 USC § 102(b) over Gren et al. (WO 00/27364) is maintained because a statement of common ownership can only be made to overcome a § 103 rejection, not a § 102 rejection. The rejection is restated to address Applicant's amendments. Applicant's arguments are addressed below.

7. The rejection of claims 1-3 under 35 USC § 102(e) over Gren et al. (US 6,911,217) is maintained. The rejection is restated to address Applicant's amendments. Applicant's arguments are addressed below.

8. The rejection of claims 1-3 and 5-14 under 35 USC § 102(b) over Nilvebrant et al. (WO 00/12069) is maintained. The rejection is restated to address Applicant's amendments. Applicant's arguments are addressed below.

9. The rejection of claims 5 and 6 under 35 USC § 103 over Gren et al. (WO 00/27364) is maintained because, although the reference was commonly owned at the time of invention, the reference, which was published more than a year before the earliest priority date of the instant application, qualifies as art under 35 USC § 102(b) and cannot be excluded by a statement of common ownership. The rejection is restated to address Applicant's amendments.

10. The rejection of claims 1-3 and 5-14 under 35 USC § 102(e) over Kreilgård et al. (6,770,295) is maintained. The rejection is restated to address Applicant's amendments. Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

> granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3 and 5-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Nilvebrant et al. (US 6,630,162, filed November 9, 2000).

13. Nilvebrant et al. teach a method of treating overactive urinary bladder comprising orally administering a formulation containing tolterodine (claim 16; column 1, lines 30-48). Nilvebrant et al. teach that the tolterodine is marketed as immediate-release tablets containing 1 mg or 2 mg doses of the tolterodine (column 1, lines 49-53). Nilvebrant et al. teach that the recommended dosage is usually taken twice daily (column 1, lines 49-53). Nilvebrant et al. teach that a clinical trial was conducted with tolterodine for the treatment of overactive bladder in patients and that the compound is marketed for the treatment of overactive bladder (column 8, lines 29-60; column 1, lines 49-55). Thus, it is clear that the method of treating overactive urinary bladder taught by Nilvebrant et al. comprising administering tolterodine is for humans. Further, because the patients enrolled in the clinical trial were included in the study due to presenting symptoms of overactive urinary bladder, it is the Examiner's position that the patients needed the treatment. Thus, the instant limitation that the tolterodine was given "when needed" is inherent in the disclosure of Nilvebrant et al. because the patients included in the clinical trial needed the treatment when they received the tolterodine. Nilvebrant et al. exemplify twice daily administration of 2 mg tolterodine in an instant-release formulation (column 8, lines 27-60). The teaching of a twice daily administration by Nilvebrant et al. anticipates the herein-claimed interval for administration of within 8-12

hours, or any of the hours within the range, because administration at an interval of more than 12 hours would be less than twice daily, and administration at an interval of less than 8 hours would be more than twice daily. Nilvebrant et al. also teach a method of treating an overactive bladder comprising orally administering tolterodine in a controlled-release formulation (claim 16; column 2, lines 19-26). Nilvebrant et al. exemplify administration of a 4 mg dose of tolterodine in the controlled-release formulation for treating overactive urinary bladder (column 8, lines 27-60). Thus, Nilvebrant et al. anticipate the instantly claimed methods.

14. Claims 1-3 and 5-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilvebrant et al. (WO 00/12069, published March 9, 2000).

15. Nilvebrant et al. teach a method of treating overactive urinary bladder comprising orally administering tolterodine to "a patient in need" (claims 1, 6 and 8). Nilvebrant et al. teach that a clinical trial was conducted with tolterodine for the treatment of overactive urinary bladder in patients (pp. 10-11). Thus, it is clear that the method of treating overactive urinary bladder taught by Nilvebrant et al. comprising administering tolterodine is for humans, and the humans receiving the tolterodine needed the treatment, as indicated in claim 1. Nilvebrant et al. exemplify twice daily oral administration of 2 mg tolterodine in an instant-release formulation (Figure 1 and p. 7, lines 31-37). The teaching of a twice daily administration by Nilvebrant et al. anticipates the herein claimed interval for administration of within 8-12 hours, or any of the hours within the range, because administration at an interval of more than 12 hours would be

less than twice daily, and administration at an interval of less than 8 hours would be more than twice daily. Nilvebrant et al. also teach a method of treating an overactive bladder comprising administering tolterodine in a controlled-release tablet for oral administration (claim 6). Nilvebrant et al. exemplify once daily oral administration of 4 mg tolterodine in the controlled-release capsule for treating overactive urinary bladder (Figure 1 and p. 7, lines 31-37). Thus, Nilvebrant et al. anticipate the instantly claimed methods.

16. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gren et al. (WO 00/27364, published May 18, 2000) and under 35 U.S.C. 102(e) over the corresponding US Patent (US 6,911,217, filed November 11, 1999).

17. Gren et al. teach a method of treating overactive bladder which comprises administering a controlled-release formulation comprising tolterodine as the active ingredient (claim 20 of '364 and claim 19 of '217). Gren et al. teach that "[t]he overactive bladder condition gives rise to urinary frequency, urgency and/or urge incontinence." (p. 6, lines 21-22 of '364 and column 4, lines 60-61 of '217). Therefore, it is clear that the method of treating urinary incontinence comprising administering tolterodine achieves symptomatic relief of urgency and/or frequency. Further, if the symptoms in the patients were relieved upon taking tolterodine, the patients clearly needed the treatment. Thus, Gren et al. anticipate the instantly claimed methods.

18. Claims 1-3 and 5-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Kreilgård et al. (6,770,295, filed August 26, 1999).

19. Kreilgård et al. teach a method of treating overactive urinary bladder comprising orally administering tolterodine, the 5-hydroxymethyl metabolite, or its racemate to a patient "in need" (claims 1, 5 and 7). Kreilgård et al. teach that a clinical trial was conducted with tolterodine for the treatment of overactive bladder in patients (column 5, line 55-column 6, line 8). Thus, it is clear that the method of treating urinary overactive bladder taught by Kreilgård et al. comprising administering tolterodine is for humans. Kreilgård et al. exemplify twice daily oral administration of 2 mg tolterodine in an instant-release formulation (Figure 1 and column 4, lines 40-46). The teaching of a twice daily administration by Kreilgård et al. anticipates the herein claimed interval for administration of within 8-12 hours, or any of the hours within the range, because administration at an interval of more than 12 hours would be less than twice daily, and administration at an interval of less than 8 hours would be more than twice daily. Kreilgård et al. also teach a method of treating an overactive bladder comprising administering tolterodine in a controlled-release tablet for oral administration (claim 5). Kreilgård et al. exemplify once daily oral administration of 4 mg tolterodine in the controlled-release capsule for treating overactive urinary bladder (Figure 1 and column 4, lines 40-46). Thus, Kreilgård et al. anticipate the instantly claimed methods.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gren et al. (WO 00/27364).

23. Gren et al. teach as stated above. Gren et al. also exemplify controlled-release formulations for administration in the method of treating overactive urinary bladder which comprise effective doses of 2 mg and 4 mg of tolterodine tartrate.

24. Gren et al. do not explicitly teach that the method is for the treatment of humans.

25. It would have been obvious to a person of ordinary skill in the art at the time of the invention to administer the controlled-release formulations comprising 2 mg or 4 mg of tolterodine tartrate to humans in a method of treating urinary incontinence.

26. The person of ordinary skill in the art would have been motivated to administer the controlled-release formulations comprising 2 mg or 4 mg of tolterodine tartrate to

humans in a method of treating urinary incontinence because Gren et al. teach the method for treatment of urinary incontinence in general and do not exclude the treatment of humans. Therefore, because no patient is excluded from the method by Gren et al., any patient with overactive urinary bladder would be treatable by the method absent evidence to the contrary. The person of ordinary skill in the art would have expected success because Gren et al. teach the method as being generally applicable to any patient, including human, with overactive urinary bladder.

Response to Arguments

27. Applicant's arguments filed August 3, 2006, have been fully considered but they are not persuasive. Applicant presents the same argument against all of the rejections under 35 USC § 102. Applicant argues that the instant claims are directed to a method of treating overactive urinary bladder comprising administering tolterodine "only when the patient feels such administration is immediately warranted or desired" (i.e., p.r.n.), whereas the cited references (Nilvebrant et al., Gren et al., and Kreilgård et al.) all teach regimented, chronic administration of tolterodine. It is the Examiner's position that the instant claims, given their broadest reasonable interpretation, also encompass administration of tolterodine to patients in need of treatment for overactive urinary bladder, as, for instance, in claim 1 of WO 00/12069 and claim 1 of US 6,770,295. In other words, the instant limitation that the tolterodine is administered "when needed" does not necessarily limit administration of the tolterodine in a p.r.n. dosing regimen. As discussed above, the patients who received tolterodine in the clinical trials also received

the treatment when needed because they received the compound after displaying the symptoms of overactive urinary bladder. This fact is reflected in the language of claim 1 of WO 00/12069 and claim 1 of US 6,770,295. Applicant's arguments regarding the p.r.n. dosing regimen relate to limitations that are not in the instant claims. Thus, the instant claims are properly rejected under 35 USC § 102 because Nilvebrant et al., Gren et al., and Kreilgård et al. all disclose administration of tolterodine in the same doses and at the same frequency as instantly claimed to patients who need treatment for the same condition as instantly claimed.

28. Regarding the rejection under 35 USC § 103, Applicant argues that WO 00/27364 is not a competent reference because it is excluded under 35 USC § 103(c) by the statement of common ownership. The rejection is maintained, however, because 35 USC § 103(c) only excludes references that qualify as art only under § 102 (e), (f), or (g). Because WO 00/27364 qualifies as art under § 102(b), it is a competent reference for rejection under § 103, despite common ownership.

29. No arguments are seen to be unaddressed.

Conclusion

30. No claims are allowed.

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Capps whose telephone number is (571) 272-8646. The examiner can normally be reached on Monday-Friday, 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER